



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

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Submission Tracking No. (STN): **103821/5015**

BioPort Corporation
Lallan Giri, Ph.D.
Vice President
Scientific Services and Regulatory Affairs
3500 Martin Luther King Jr. Blvd.
Lansing, MI 48906

Dear Dr. Giri:

The Labeling Supplement to your License Application for Anthrax Vaccine Adsorbed, to include updating of the package insert, package, and container labels, has been approved. This information will be placed in your License Application file for this product.

Please submit four copies of final printed labeling at the time of use and include the label transmittal Form FDA 2567 with completed implementation information.

Sincerely yours,

Karen L. Goldenthal, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachments: BioThrax Package Insert, Package, and Container
Labels/Forms 2567